



Post Authorisation Assessments

Lincocin Premix 44 g/kg Premix for Medicated Feed

•	06 July 2016	Change in the batch size (including batch size ranges) of the finished product. Change in the specification limits of the finished product Change in the specification parameters of the finished product Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product
•	24 May 2016	Deletion of a manufacturing site.
•	27 April 2016	Submission of an updated certificate of suitability.
•	03 November 2015	Change in immediate packaging of the finished product.
•	13 November 2014	Submission of a new and an updated Ph. Eur. Certificate of Suitability.
•	01 July 2014	Deletion of a manufacturer of the active substance.
•	07 August 2013	Transfer of Marketing Authorisation Holder (including a change in distributor). Change of name of the Manufacturer of the finished product. Addition of an alternative batch release site.
•	09 January 2013	Deletion of a batch release site. Deletion of a batch testing site.
•	20 November 2012	Variation to update the Certificate of Suitability for the Active Substance.
•	15 December 2009	Variation to submit a new European Pharmacopoeia Certificate of Suitability from an additional supplier for the Active Substance. Deletion of a supplier of the API. Addition of a Manufacturer of the Active Substance.
•	09 December 2009	Variation to submit an updated European Pharmacopoeia Certificate of Suitability.
•	08 July 2009	Change in the test procedure of the finished product..
•	23 April 2009	Variation to seek approval for the addition of a new site for QA testing.
•	09 October 2007	Variation to change the Active Substance Manufacturer.
•	15 August 2007	Change in test procedure of the finished product.
•	15 August 2007	Addition of a Manufacturer/Assembler of Dosage Form.
•	06 June 2007	Variation to bring SPC/ Labelling in line with the Veterinary Regulations, 2005. Transfer of legal category from POM to POM-VPS.

•	03 May 2007	Renewal.
•	30 June 2005	Variation concerning the addition of a Distributor.
•	10 December 2004	Change in the name of the Active Substance Manufacturer.
•	30 November 2004	Change in the name of a Manufacturer.
•	04 November 2004	Change in the Marketing Authorisation Holder.
•	25 June 2004	Renewal.
•	28 August 2003	Variation to add an additional Distributor.
•	13 December 2001	Change of Marketing Authorisation Holder. Change of Manufacturer/Assembler of Dosage Form.
•	06 October 1999	Change in the finished product specification.
•	18 August 1999	Change in the name of the Assembler of Dosage Form.
•	05 October 1998	Combination of two Marketing Authorisations into one.